

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)
THIS DOCUMENT RELATES TO ALL CASES	

**PLAINTIFFS' BRIEF IN SUPPORT OF *DAUBERT*
MOTION TO PRECLUDE OPINIONS OF
DEFENSE EXPERT JANICE K. BRITT, PH.D.**

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PRELIMINARY STATEMENT

Janice Britt, Ph.D., a toxicologist retained by Defendants, submitted a report of more than 100 pages, disputing general causation. However, at her deposition, Dr. Britt agreed [REDACTED]

[REDACTED].

She also confirmed that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Aside from the questionable admissibility of EBT, [REDACTED]

[REDACTED].

Dr. Britt ignored and did not factor in significant categories of evidence that strongly support the scientific consensus that NDMA and NDEA are probable human carcinogens, including animal studies, dietary studies, and mechanistic studies—all of which were taken into account by Plaintiffs' general causation experts. This is a fundamental methodological flaw, with or without regard to the failure to comply with her proffered methodology. Dr. Britt also admitted

[REDACTED]

[REDACTED], precluding her from reliably resting her opinions on those studies as well.

Dr. Britt's opinions are unsupported by any properly applied, accepted methodology, requiring preclusion of her opinions.

STATEMENT OF FACTS

Dr. Britt is a toxicologist.¹ Dr. Britt's report professes to answer the question of whether NDMA and NDEA can be carcinogenic to humans. (Expert Report of Janice K. Britt, Ph.D., p. 10 [hereinafter, the "Britt Report"], Ex. D). The report concludes that the answer is no in the context of the doses taken and duration of use, at issue here. (*Id.* at 28). In her deposition, this was refined: [REDACTED]

[REDACTED] (9/23/2021 Janice K. Britt Dep. Tr. 140:2-8; Ex. E).

However, Dr. Britt's deposition testimony presented a quite different picture than her report, fatally undercutting the opinions. In fact, Dr. Britt acknowledged [REDACTED]

[REDACTED]. Rather, [REDACTED]

¹ Dr. Britt is employed by ToxStrategies, a company known as a go-to chemical industry defender. The Center for Public Integrity, *How Industry Scientists Stalled Action on Carcinogen* (May 19, 2014), <https://tinyurl.com/zyp3zn5j> (stating that "the American Chemistry Council, the industry's main trade group and lobbyists, hired ToxStrategies Inc., a Texas-based firm with scientists experienced in poking holes in research that links chromium to cancer") (Ex. A to Adam M. Slater's Certification in Support of Plaintiffs' Motion to Exclude Dr. Janice K. Britt's Opinions (unless otherwise noted, all exhibits cited in this brief are attached to this supporting certification)); Natural Resources Defense Council, Comments from NRDC on EPA's TSCA Systematic Review (Aug. 16, 2018), <https://tinyurl.com/att66nas> (stating: "[R]ecently the ToxStrategies consulting firm published a list of biases with the TCE heart studies that it contends should make the study unusable for regulatory purposes. Its analysis and conclusion follow the criteria laid out in the TSCA systematic review. Significantly, ToxStrategies received funding from Entek International, whose Oregon-based battery parts operations have been repeatedly fined for violations related to its TCE pollution, including allegedly poisoning its workers. (The Oregonian, May 5, 2017). Thus, ToxStrategies itself also had a financial bias – something that the TSCA Systematic Review does not include in the risk of bias analysis, as discussed further below." (footnote omitted)) (Ex. B); The Roanoke Times, *FERC study finds no risk from protective coating of Mountain Valley Pipeline* (Oct. 8, 2020), <https://tinyurl.com/czeps68v> (stating, "The report cites the conclusion of ToxStrategies, a consulting firm hired by Atlantic Coast that there should be no impact on human health or the environment from the chalky residue that forms on the pipes after prolonged exposure to sunlight") (Ex. C).

[REDACTED]

[REDACTED]. (*Id.* at 64:21-65:9, 257:2-258:13).

Dr. Britt has not performed any prior scientific work regarding the subject matter here. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(*Id.* at 171:13-172:15). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(*Id.* at 39:13-56:6).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (9/23/2021 Janice K. Britt Dep. Tr. 303:12-304:1 (quoting Roberts, Jordan, Warren, Britt, & James, *Evaluation of the carcinogenicity of 1,1-dichloroethylene (vinylidene chloride)*, REGUL. TOXICOL. PHARMACOL. 35, 44-55 (Feb. 2002), Ex. F) (emphasis added)).

Dr. Britt also clearly conceded [REDACTED]. First, she conceded [REDACTED]. [REDACTED]. [REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 186:20-187:15, 209:19-210:24). However, in direct contradiction to this admission, [REDACTED]. [REDACTED] (9/23/2021 Janice K. Britt Dep. Tr. 256:11-19). Thus, she admitted [REDACTED]. [REDACTED]. [REDACTED], Dr. Britt admitted [REDACTED]. [REDACTED]. (*Id.* at 245:24-246:5, 250:4-9). She also authored a chapter in a toxicology textbook published by her then co-worker Robert C. James, Ph.D., which stated that NDMA was reasonably anticipated to be a human carcinogen. ([REDACTED] Williams, James, & Roberts, *Principles of Toxicology: Environmental and Industrial Applications*, p. 305-06 (John Wiley & Sons, Inc. 2000), Ex. G)). Finally, [REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 198:21-199:6). This testimony was given against the backdrop of Dr. Britt's published Letter to the Editor of a peer-reviewed journal, stating in part, "The International Agency for Research on Cancer (IARC) and USEPA have long determined human causation based on human data of sufficient strength and consistency that are capable of confirming or denying the hazards suggested by animal studies." ([REDACTED] James, Britt, Halmes, & Guzelian, *Comments on recent discussions*

providing differing causation methodologies, HUM. EXP. TOXICOL. 33, 110 (Jan. 2014), Ex. H)).

Thus, she has validated the methodology utilized by IARC in reaching its conclusion.

A. Dr. Britt's Limited Qualifications.

Dr. Britt testified in her deposition that [REDACTED]

[REDACTED] (9/23/2021 Janice K. Britt Dep. Tr. 81:18-20, 82:18-83:10, 91:8-17, 266:1-12). She also confirmed that [REDACTED]

[REDACTED]. (*Id.* at 205:11-21). Dr. Britt testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(9/23/2021 Janice K. Britt Dep. Tr. 241:12-244:15 (discussing Pottegård, Kristensen, Ernst, Johansen, Quartarolo, & Hallas, *Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study*, B.M.J. 12, 362 (Sept. 2018), Ex. I; Gomm, Röthlein, Schüssel, Brückner, Schröder, Heß, Frötschl, Broich, & Haenisch, *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer: A Longitudinal Cohort Study Based on German Health Insurance Data*, DEUTSCHES AERZTEBLATT INTERNATIONAL 118, 357-62 (2021), Ex. J)). However, [REDACTED]

[REDACTED]

² Dr. Britt explained that she chose to defer to the defense expert epidemiologist rather than the Plaintiffs' expert epidemiologist because she believed the defense expert to have employed a more reliable methodology—but then was unable to give any information about the respective methodologies utilized by the defense and plaintiff experts. (9/23/2021 Janice K. Britt Dep. Tr. 83:11-86:2). Thus, she arbitrarily relied on the defense rather than plaintiff experts, based on the conclusions reached, not based on scientific reasoning.

[REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 243:13-45:6). For example, [REDACTED]

[REDACTED]. (*Id.* at 244:21-245:6, 247:15-248:2, 253:16-2).

B. Dr. Britt's Failure to Utilize an Accepted Methodology.

Dr. Britt utilized a proposed methodology described as "Evidence Based Toxicology" ("EBT"). ([REDACTED] Britt Report, p. 10, 13, 19, 28). Dr. Britt conceded that

[REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 226:22-227:9, 232:9-23, 234:11-235:11). [REDACTED]

[REDACTED] (*Id.* at 224:3-226:16, 261:10-14).

[REDACTED], substantial criticisms have been leveled against this proposed methodology, which claims to borrow from the principles established for Evidence-Based Medicine ("EBM"). EBM is an approach used by physicians to establish treatment protocols, **not** to establish causation of disease (though Dr. Britt surprisingly claimed not to be aware of these published criticisms). For example, in an article titled, *Evidence-Based Toxicology: "Sound Science" in New Disguise*, the authors state in part, "The 'evidence-based toxicology' proposed by Guzelian et al. departs radically from state-of-the-art toxicology by claiming that risks for humans can only be determined on the basis of human evidence [risks that have been epidemiologically proven in humans].... **The slogans 'sound science' and 'evidence-**

based toxicology’ have both been put forward by persons with a history of extensive involvement with the tobacco industry.” Rudén & Hansson, *Evidence-based toxicology: "sound science" in new disguise*, INT. J. OCCUP. ENVIRON. HEALTH 14, 299 (Oct. 2008) [hereinafter “Rudén”], Ex. K, emphasis added. The article continues, in criticizing the proposed new methodology:

- “This line of argument is nothing less than a denunciation of state-of-the-art toxicological risk assessments. The generally accepted ideal for such assessments follows the pattern endorsed by the National Academy of Sciences. Such risk assessments should be based on a careful collection and evaluation of all the relevant evidence of sufficient scientific quality, including human, animal, *in vitro*, and other types of data, in an overall assessment that describes both the established and the likely health effects that different exposures to the agent in question can cause. Major organizations conducting state-of-the-art toxicological risk assessments have repeatedly emphasized the importance of collecting and combining all the relevant evidence, including both studies of animal models and studies of effects in exposed humans.”
- “The major difference between state-of-the-art toxicological risk assessments and Guzelian et al.’s ‘evidence-based toxicology’ is that the latter, if fully implemented, deprives risk assessors of most toxicological evidence.”
- “Similarly, in the IARC’s classification system for carcinogens, Guzelian et al.’s criteria can only be satisfied by substances classified in Group 1, ‘the agent is carcinogenic to humans,’ for which conclusive human data is required.”

- “Despite their appeal to EBM and appropriation of its terminology, what Guzelian et al. really do is to apply its principles inversely: They take the criteria used in EBM for the proof of therapeutic effects, and apply these same criteria in what they call ‘evidence-based toxicology,’ but for adverse effects.”
- “It should be obvious that the principles of EBM are opposed to the principles of EBT and cannot in any way be used as an argument for allowing significant human exposure to chemical substances, whether pharmaceuticals or other types of compounds, that have not been subject to toxicity testing or for which animal tests indicate that the substance is highly toxic. **Guzelian et al.’s attempt to use EBM, with its strong reliance on prior animal testing, as an argument for dismissing animal data from risk assessment, is such a bizarre argument that it was initially a riddle for us how it could at all be seriously put forward.**”
- “As should be clear from the above, Guzelian et al.’s views on risk assessment are implausible and not mainstream when considered in relation to well-established principles in toxicological risk assessment.”
- “Guzelian et al.’s proposal is connected to both the tobacco industry and to litigation concerning potential toxic injuries.... Philip S. Guzelian has a background as a consultant for the tobacco industry. During his time affiliated with Philip Morris he was paid about \$100,000 per year.... He acts regularly as an expert giving testimony in litigation matters when workers claim to have sustained an occupational toxic injury.... For all of his medico-legal work he has received approximately \$500,000 to \$1,000,000 per year according to his own testimony. In all these cases but one has he testified on behalf of an industry defendant.”

Rudén, at 299, 301-305, emphasis added. Dr. Britt never addressed these methodological criticisms in her report [REDACTED].

Finally, in the 2015 article co-authored by Dr. Britt along with Dr. Guzelian and Dr. James about their proffered EBT methodology, they acknowledged that EBT had still not been adopted as a recognized reliable methodology in the field of toxicology: “So, on this 10th anniversary, **we renew our suggestion that toxicologists likewise adopt evidence-based causation logic when addressing causal issues.**” James, Britt, Halmes, and Guzelian, *Evidence-based causation in toxicology: A 10-year retrospective*, HUM. EXP. TOXICOL. 34, 1250 (Dec. 2015) (emphasis added), Ex. L. As Dr. Britt admitted, [REDACTED].

C. Dr. Britt Failed to Properly Apply Her Chosen “Methodology.”

Dr. Britt testified that [REDACTED]
[REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 215:5-216:8, 228:23-229:8). Yet, **Dr. Britt admitted that** [REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 148:18-149:3). This methodological shortcoming is proven by Dr. Britt’s own writings. Dr. Britt wrote an article published in 2016 titled: *The Role of Systematic Review in the Practice of Toxicology and Risk Assessment – An Appreciation for the Primary Tool in Evidence-Based Practice*, TOXICOLOGY: OPEN ACCESS 2, 1, Ex. M. Among other things, Dr. Britt conclusively stated in her article that a properly conducted systematic review is essential to—“the primary tool”—for the proper application of EBT. For example:

- “[T]he field as a whole has yet to develop an appreciation of the rigor required to adequately utilize the systematic review as the **primary tool** in evidence-based toxicology (EBT).”

- “[S]ome of the exercises that differentiate the systematic review from a standard narrative review include: development and publication of a protocol, documentation of the literature search (including documentation of all records that were included/excluded), and a critical evaluation of each study using an approach determined a priori.”
- “As we go forward, we must not haphazardly use the term systematic review, as it clearly bears weight – too often, already, the term is misused, referring only to elements of an exercise that were conducted systematically.... We must...develop a greater appreciation for the tool that allows us [to] conduct evidence-based toxicological assessments.”

Id. at 1 & 3, emphasis added. In the EBT article authored by Dr. Britt in 2015, she described the systematic review as one of the “fundamental concepts that form EBT.” James, Britt, Holmes, and Guzelian, *Evidence-based causation in toxicology: A 10-year retrospective*, *Hum. Exp. Toxicol.* 34, 1245 (Dec. 2015), Ex. L. [REDACTED] she failed to properly apply her proposed EBT methodology—based on her own publications.

In addition to the failure to conduct a systematic review, Dr. Britt conceded that [REDACTED]

[REDACTED]:

- [REDACTED]
[REDACTED]
[REDACTED] (9/23/2021 Janice K. Britt Dep. Tr. 255:15-256:4).
- [REDACTED]
[REDACTED]
[REDACTED] (*Id.* at 256:11-19). [REDACTED]
[REDACTED] the statement in her 2015 publication that: “In a similar vein, while our original article stated (and we still accept as true) that human data are the most valid metric

to determine human causality, EBT does not call for eliminating the consideration of animal studies. In fact, our publications have consistently argued that when human data are insufficient to answer human causation and human risk questions the regulatory risk assessment process will derive conservative, health-protective exposure guidelines in the interim.” James, Britt, Halmes, and Guzelian, *Evidence-based causation in toxicology: A 10-year retrospective*, HUM. EXP. TOXICOL. 34, 1246 (Dec. 2015), Ex. L.

- [REDACTED]
[REDACTED]
[REDACTED]

(9/23/2021 Janice K. Britt Dep. Tr. 257:2-18).

- [REDACTED]
(*Id.* at 266:1-12, 271:17-272:8).

Thus, in applying her proffered methodology, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED], appear to be the only studies she actually relied on.

THE DAUBERT STANDARD

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. “As a gatekeeper, courts are supposed to ensure that the testimony given to the jury is reliable and will be more informative than confusing.” *In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017). Additionally, “[b]oth an expert’s methodology and the application of that methodology must be reviewed for reliability.” *Id.* at 791. The “specific

way an expert conducts such an analysis must be reliable; **‘all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary,** but must itself be **based on methods of science.’”** *Id.* at 796. Here, the application of the proposed methodology is fatally flawed.

The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417-18 (3d Cir. 1999). An “expert’s opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, “the expert must have ‘good grounds’ for his or her belief.” *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, “any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *Id.* at 745. A court should also consider the methodology’s error rate when assessing its reliability. *Paoli*, 35 F.3d at 742 n.8. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Id.* at 742 (discussing reliability factors under *Daubert* and Third Circuit case law). The EBT methodology proposed by Dr. Britt was built for litigation.

Furthermore, “*Daubert’s* gatekeeping requirement make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); see also *Magistrini v. One Hour Martinizing Dry*

Cleaning, 180 F. Supp. 2d 584, 594 (D.N.J. 2002), *aff'd*, 68 Fed. Appx. 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

(i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.*, 29 F.3d 499 (9th Cir. 1994)).

Magistrini, 180 F. Supp. 2d at 594–95. To this end, the Third Circuit has affirmed the exclusion of expert testimony that “failed to consistently apply the scientific methods ... articulate[d], ... deviated from or downplayed certain well-established principles of [the] field, and ... inconsistently applied methods and standards to the data so as to support [an] a priori opinion.” *Zoloft*, 858 F.3d at 792. The same outcome is required on this record.

I.
DR. BRITT’S OPINIONS
SHOULD BE PRECLUDED PURSUANT TO DAUBERT

Dr. Britt’s opinion on general causation, the question she sought to answer, rests on her application of the proposed EBT methodology she has been promoting. This is not an accepted methodology [REDACTED], which is fatal to her proposed testimony. *See Zoloft*, 858 F.3d at 791. Moreover, it was designed specifically for the benefit of industry in litigation and regulatory disputes. *Rudén*, at 305. This further undercuts the reliability and admissibility of Dr. Britt’s opinions. *See Paoli*, 35 F.3d at 742; *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 241 (S.D.N.Y. 2018) (holding, “[M]ethodology ... aimed at achieving one result ... is unreliable, and ... must be excluded” (quoting *Faulkner v. Arista Records LLC*, 46 F. Supp. 3d 365, 381 (S.D.N.Y. 2014))).

In fairness, there is an unpublished decision permitting Dr. Philip Guzelian (one of the co-authors of the two articles cited above regarding EBT) to testify to his opinion denying general causation regarding a chemical known as trichloroethylene (“TCE”). That non-precedential, unpublished decision from a Federal Court in Missouri, recognized the problems with asserting EBT as a reliable methodology. For example, “The notable characteristic of this methodology is that it makes it more difficult for toxic tort plaintiffs to establish general causation. This is particularly true with respect to substances, like TCE, that cannot ethically or legally be tested on humans.” *Kirk v. Schaeffler Group USA, Inc.*, No. 3:13-cv-5032-DGK, 2015 WL 12426834, at *2 (W.D. Mo. 2015), Ex. N. However, it appears that a major factor in that Court’s decision to permit the testimony despite its concerns was that “his report applies nine well-established guidelines, commonly known as the Bradford Hill criteria, to analyze whether TCE has been shown to cause AIH in humans,” “and he reviewed exhaustively the published human and animal studies.” *Id.* In sharp contrast, [REDACTED]

[REDACTED].

Plaintiffs also note that in *Kirk*, the court did not address Rudén’s devastating critique of EBT. Among other criticisms, Dr. Rudén wrote:

Exclusive reliance on the type of human evidence that Guzelian et al. refer to makes sense if the only concern is to avoid false positives. However, if false negatives are also a concern, then this approach is not optimal. The risk of false negatives is substantial even in large, well-conducted epidemiological studies. This is, of course, one of the major reasons why animal and in vitro experiments are performed at all.

Rudén, at 305. In terms of *Daubert*, this means that EBT’s rate of error is scientifically unacceptable and requires exclusion under *Daubert*. See *Paoli*, 35 F.3d at 742 n.8. It also supports Dr. Rudén’s conclusion that EBT’s creators designed it as a tool for their use as paid industry

experts. To be clear, this Court should not condone an expert's exclusion of scientifically relevant evidence simply because they have committed to doing it in every case under the abstract guise of a "scientific methodology." *See Mirena II*, 341 F. Supp. 3d at 241 (holding, "Opinions that assume a conclusion and 'reverse-engineer[] a theory' to fit that conclusion are, similarly, inadmissible").

Perhaps worse, Dr. Britt admitted that [REDACTED]
[REDACTED]. (9/23/2021 Janice K. Britt Dep. Tr. 280:17-281:17). This type of willful ignorance runs completely counter to the scientific rigor required of experts under *Daubert*, and clearly establishes that Dr. Britt's methodology and her entire approach to toxicology is impermissibly "aimed at achieving one result," and thus "unreliable, and ... must be excluded." *Mirena II*, 341 F. Supp. 3d at 241. [REDACTED]
[REDACTED]

However, the Court need not even reach the question of whether EBT is an accepted methodology, since Dr. Britt admitted that [REDACTED]
[REDACTED]. *See Zoloft*, 858 F.3d at 791-92.

In granting a motion to preclude an expert under *Daubert*, this Court has observed:

[C]ourts also need not admit mere conclusions or opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.... Mere assumptions, without causal evidence or methodological analysis may be inadmissible.... Conclusions based only on the expert's experience, and testimony founded on methods that are not generally accepted or lack testable hypotheses may also fail to surmount the *Daubert* standard.

Player v. Motiva Enterprises LLC, No. Civ. 02-3216(RBK), 2006 WL 166452, at *6-7 (D.N.J. Jan. 20, 2006) (citations omitted), Ex. O. In *Player*, this Court found the expert failed to satisfy the reliability requirement, as the expert failed to consider important facts without satisfactory

explanation, among other things. *Id.* at *7. The Court held: “His method is untestable and arbitrary, without a generally accepted, established, or peer reviewed methodology, and his evaluation was conducted without any real standards.” *Id.* at *8. [REDACTED]

[REDACTED]

[REDACTED]

On top of these methodological failings, Dr. Britt was [REDACTED]
[REDACTED]. This lack of knowledge and experience should result in greater scrutiny of the method actually applied by the expert. *See Elcock*, 233 F.3d at 747 (quoting *Paoli*, 35 F.3d at 742, n.8). Dr. Britt also [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (9/23/2021 Janice K. Britt Dep. Tr. 39:12-56:6, 86:7-24, 301:11-304:1 (quoting Roberts, Jordan, Warren, Britt, & James, *Evaluation of the carcinogenicity of 1,1-dichloroethylene (vinylidene chloride)*, REGUL. TOXICOL. PHARMACOL. 35, 44-55 (Feb. 2002) (emphasis added), Ex. F)). This should factor into the Court’s determination of reliability:

One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture. But in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1995). Expert testimony prepared solely for purposes of litigation, as opposed to testimony flowing naturally

from an expert's scientific research or technical work should be viewed with some caution. *Magistrini*, 180 F. Supp. 2d at 594.

In addition, Dr. Britt's opinion in her report disputing that there is adequate proof of general causation is inconsistent with the prevailing scientific consensus that NDMA and NDEA are probable human carcinogens, and her own admission that [REDACTED] [REDACTED]; thus, the method that yielded the opinion in the report should be scrutinized quite closely. *See In re Zolof Products Liability Litigation*, 26 F. Supp. 3d 449, 460-61 (E.D. Pa. 2014) (citing *In re Rezulin Products Liability Litigation*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (“**[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.**”)). The FDA has concluded that “NDMA and NDEA are probable human carcinogens and should not be present in drug products,” the EPA considers NDMA and NDEA to be probable human carcinogens, and USP has said, “their presence in medicines, even at trace level is considered unacceptable because Nitrosamine impurities are probable human carcinogens.” (FDA, *FDA presents interim limits of nitrosamines in currently marketed ARBs* (Dec. 19, 2018), <https://tinyurl.com/4rkpdf5h>; EPA, *N-Nitrosodimethylamine*, <https://tinyurl.com/9krh69u9>; EPA, *N-Nitrosodiethylamine*, <https://tinyurl.com/48y7nejw>; USP, Summary, Highlights and Timeline of General Chapter <1469> Nitrosamine Impurities (July 20, 2018), Exs. P, Q, R, & S respectively). [REDACTED]

[REDACTED]

[REDACTED] (SOLCO00024226, ZHP 129, Ex. T). Yet, Dr. Britt made no effort in her report [REDACTED]

[REDACTED] to contend with scientific literature that was inconsistent with the ultimate opinion stated

in her report, and [REDACTED] the conclusion by IARC that NDMA and NDEA are probable human carcinogens.

A. Inadequate Application of the Proposed EBT Methodology.

In order for Dr. Britt's opinions to be admissible, "the process or technique used in formulating the opinion [must be] ... reliable," and the principles and methods employed by the expert [must be] . . . applied reliably to the facts of the case. *Pineda*, 520 F.3d at 247 (citing *Paoli*, 35 F.3d at 742); *see also* Fed. R. Evid. 702, Advisory Committee's Note. "[A]n expert may not 'pick and choose' from the scientific landscape and present the Court with what he believes the final picture looks like." **Where an expert ignores evidence that is highly relevant to his [or her] conclusion, contrary to his [or her] own stated methodology, exclusion of the expert's testimony is warranted.** *Mirena II*, 341 F. Supp. 3d at 242 (quoting *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 563 (S.D.N.Y. 2004)).

Here, Dr. Britt admitted that [REDACTED]

[REDACTED].
This admission establishes that the proffered methodology was not reliably applied, and requires preclusion of the opinions founded on that methodology. *Zolof*, 858 F.3d at 792.

[REDACTED] Dr. Britt also admitted that [REDACTED]

[REDACTED] This includes [REDACTED]

[REDACTED] This renders her methodology unreliable and requires the exclusion of her opinions. *See Zolof*, 858 F.3d at 796; *Mirena II*, 341 F. Supp. 3d at 242.

Finally, [REDACTED]
[REDACTED], Dr. Britt confirmed that [REDACTED]
[REDACTED]
[REDACTED]. [REDACTED]
[REDACTED]
[REDACTED]

Whether this is considered to be a lack of qualification, a methodological flaw, or both, the bottom line is she cannot be permitted to rely on those studies because [REDACTED]
[REDACTED]

[REDACTED]. Indeed, in order to ensure that the methodology is truly a methodology, rather than a mere conclusion-oriented selection process, there must be a scientific method that is used and explained. *Magistrini*, 180 F. Supp. 2d at 607. Dr. Britt selected the conclusions. This is not to say that Dr. Britt needed to recalculate the entire statistical analysis, but an expert's failure to comment on the potential weaknesses of the studies upon which an expert relies nor to acceptably explain why she did not accord more weight to other studies that did not align with her conclusions may render the opinion unreliable. *Magistrini*, 180 F. Supp. 2d at 584. In essence, Dr. Britt's methodology required her to exclude non-epidemiological evidence, and her lack of epidemiological expertise prevented her from reliably evaluating the only evidence left for her to reach an opinion on whether NDMA or NDEA can cause cancer in humans – she painted

herself into this corner and cannot get out. To reach an opinion on general causation in this case, she simply assumed the studies supported the position of her client. This is arbitrary and runs counter to even the most basic precepts of the scientific method. This Court should consequently exclude Dr. Britt's opinions. *See Zoloft*, at 796, 800.

CONCLUSION

For the foregoing reasons, Dr. Britt should be precluded from offering her opinions related to general causation.

Respectfully,

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Dated: November 1, 2021